Remarks

Claims 15-23 and 26-36 are pending in the present application. Claims 15-23 and 26 have been rejected by the Examiner.

By the above amendments, Claim 26 has been amended to more particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants submit that the amendments are fully supported by the specification as filed (*see, e.g.*, page 6, lines 5-7), and no new matter is being added.

By the above amendments Claims 27-36 have been cancelled without prejudice, in response to the Examiner's maintenance of the restriction requirement. The amendments canceling Claims 27-36 are being made solely to advance the prosecution of the instant application and are not in any way to be construed as an admission that the canceled material is unpatentable. Thus, Applicants reserve the right to pursue coverage of the canceled material by filing a continuation or a divisional application at an appropriate time in the future.

Claims 15-23 and 26 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over the combination of PDR (page 2058 of the 52d edition) and U.S. Patent 5,260,072 and U.S. Patent 5,133,974.

Applicants respectfully traverse the rejection. Applicants submit that neither Roche in US Patent 5,260,072 nor Paradissis in US Patent 5,133,974 disclose formulations of topiramate comprising core particles as claimed in the present invention nor teach or disclose the use of such formulations for the treatment of convulsions by sprinkling onto soft food and swallowing.

Further, Applicants submit that neither the Roche et. al., nor the Paradissis et al., formulations would be suitable for sprinkling onto soft food and swallowing, as is required in the presently claimed invention. Roche et al., teach a chewable taste-masked tablet formulation which cannot be sprinkled and swallowed. Paradissis et al., teach a controlled release capsule which is intended to be swallowed intact in order to provide the desired release profile. Therefore, Applicants maintain that the teachings in the PDR, Roche et al., and Paradissis et al., would not render obvious the present invention.

Additionally, Applicants submit that the pharmaceutical compositions of the claimed invention result in a product which was unexpectedly found to have a superior stability profile over prior art tablet formulations of topiramate. Applicants unexpectedly found that the coating used to taste mask the topiramate core beads also provides a barrier to the absorption of moisture, and therefore, improves on the stability of the sprinkle formulation. Although it was necessary to put a desiccant into the bottles to stabilize the topiramate tablet formulation for storage, the sprinkle formulation does not require a desiccant. There is no need for a desiccant in spite of the fact that the capsules which are used to encapsulate the appropriate dosage of sprinkles contain more than 10% moisture by weight; it appears that this moisture does not accelerate the degradation of topiramate because of the taste mask coating for the sprinkles. (see page 17, lines 7-16 of the specification). This was a surprising and unexpected finding by Applicants, which was in no way suggested by the prior art, either alone or in combination.

Applicants maintain that the claimed methods of the present invention are not obvious over the PDR, US Patent 5,260,072 and US Patent 5,133,974, either alone or in combination, and respectfully request that the rejection be withdrawn.

In view of the above remarks, Applicants maintain that the application is in condition for allowance and passage to issue is earnestly requested.

Respectfully submitted,

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